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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/692,055	10/22/2003	Craig D. Friedman	501438.20501	7247
54042 7590 01/23/2008 WOLF, BLOCK, SHORR AND SOLIS-COHEN LLP 250 PARK AVENUE 10TH FLOOR NEW YORK, NY 10177				
			EXAMINER HAGOPIAN, CASEY SHEA	
			ART UNIT 1615	PAPER NUMBER
			NOTIFICATION DATE 01/23/2008	DELIVERY MODE ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PTO@WOLFBLOCK.COM

Office Action Summary	Application No. 10/692,055	Applicant(s) FRIEDMAN ET AL.	
	Examiner Casey Hagopian	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 November 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-12, 61, 63-69, 72-76 and 79-83 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2, 3, 5, 7-12, 61, 63-69, 72, 73, 76 and 79-83 is/are rejected.
- 7) ☒ Claim(s) 4, 6 and 75 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Receipt is acknowledged of applicant's Amendment/Remarks filed 11/2/2007.

Claims 2 and 4 are currently amended. Claims 1, 13-59 and 78 have been cancelled. Claims 2-12, 61, 63-69, 72-76 and 79-83 are currently pending.

Response to Arguments

The amendment renders the rejection of claim 4 under 35 USC 112, 2nd paragraph moot. Thus, the rejection of claim 4 under 35 USC 112, 2nd paragraph has been withdrawn.

The amendment renders the rejection of the claims under 35 USC 103 in view of Reich and Gould moot. Thus, the rejection under 35 USC 103 in view of Reich and Gould has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Thomson (US 2002/0018884 A1).

NEW OBJECTIONS/REJECTIONS

The following objections/rejections are newly added:

Claim Objections

Claim 8 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim: Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Said claim includes the

limitations "the scaffold comprises a hydrophobic polyurethane". It does not appear to further limit claim 2 since the scaffold in claim 2 is hydrophobic and containing a polyurethane. Correction is respectfully requested.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 6, 7, 10, 68, 69, 82 and 83 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 6 recites the limitation "at least one therapeutic agent". There is insufficient antecedent basis for this limitation in the claim.

Claim 7 the limitation "wherein the coating contains enzymes". Are said enzymes limiting the one or more therapeutic agents recited in claim 2 or is the composition further containing enzymes additional to the one or more therapeutic agents? Correction is respectfully requested.

Claim 10 is recites the limitation "the therapeutic agent". There is insufficient antecedent basis for this limitation in the claim.

Claims 68 and 69 include the limitation "wherein the scaffold material". There is insufficient antecedent basis for this limitation in the claim.

Claims 82 and 83 include the limitation "wherein the void phase". There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claim 2, 5, 7-12, 61, 63-67, 72-74, 76, and 79-83 are rejected under 35 U.S.C. 102(a/e) as being anticipated by Thomson (US 2002/0018884 A1).

Thomson teaches a foam composite comprising reticulated hydrophobic polyurethane foam substrate that is coated with a coating comprising a hydrophilic polyurethane prepolymer (paragraph 0012; Figure 1). Said hydrophilic coating can be a hydrophilic polyurethane foam coating (paragraph 0015). Thomson also teaches embodiments that include an active ingredient in the hydrophilic coating (paragraph 0014). Said active ingredients include pharmaceutical, enzymes and human cells (paragraph 0147). Figure 20 illustrates a particular drug delivery embodiment. Thomson teaches void volumes of up to 98% and pore size from 4 to 100 pores per linear inch (ppi) (paragraph 0070). Regarding the limitations of claims 79-81, absent of a showing of evidence to the contrary, said pore sizes taught by Thomson read on the pore sizes claimed. Regarding the limitations of claims 11 and 12, Thomson teaches various shapes (paragraph 0071). It is also noted that generally limitations drawn to

shapes are not accorded patentable weight (see MPEP 2144.04 (I) and (IV)(A)-(B)). Regarding the limitations of claims 5, 61 and 63-67, said limitations are considered taught by the prior art, because the prior art teaches the claimed invention comprising the same materials. Regarding claims 73 and 74, Thomson contemplates coatings in the form of films and hydrogels (paragraphs 0092-0097 and 0130). Regarding claim 76, the polyurethane coating and hydrogels mentioned previously read on non-biodegradable polymers as evidenced by paragraph 00179 of the instant specification.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein

were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 3, 68 and 69 are rejected under 35 U.S.C. 103(a) as being unpatentable over Thomson (US 2002/0018884 A1) in view of Pinchuk (USPN 5,229,431).

Thomson teaches the elements discussed above. Thomson is silent to including an agent into the scaffold as well as the particular scaffold material being polycarbonate polyurethane. Pinchuk teaches a polycarbonate urethane foam suitable for medical prosthesis and implants (abstract). Said suitable medical prosthesis and implants include drug eluting matrices (col. 3, line 4). One of ordinary skill in the art would be motivated to include the particular material polycarbonate urethane because of its crack-resistant, elastomeric and pliable properties (abstract). A practitioner would reasonably expect said material to withstand the stresses and degradation conditions once implanted in the body. One skilled in the art would additionally expect inclusion of an agent within the matrix to effectively elute into the body. Thus, in Thomson, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include the particular material polycarbonate urethane as well as an active agent as suggested by Pinchuk.

Double Patenting

Applicant is advised that should claim 4 be found allowable, claim 6 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Conclusion

Claims 4, 6 and 75 are objected to as being dependent on a rejected base claim. All claims have been rejected/objected to; no claims are allowed.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Casey Hagopian whose telephone number is 571-272-6097. The examiner can normally be reached on Monday through Friday from 7:00 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Carlos Azpuru, can be reached at 571-272-0588. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for

Application/Control Number:
10/692,055
Art Unit: 1615

Page 8

published applications may be obtained from either Private PAIR or Public PAIR.

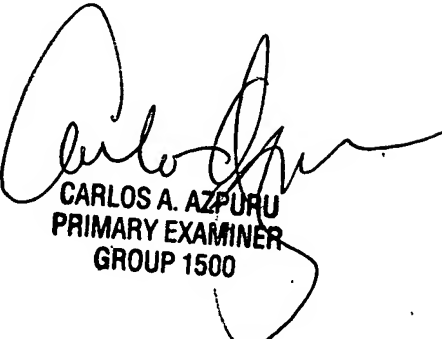
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Business Center (EBC) at 866-217-9197 (toll-free).

/Casey Hagopian/

Casey Hagopian
Examiner
Art Unit 1615



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